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# In the Supreme Court of the United States

OCTOBER TERM, 1958

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No. 27

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION  
AND WELFARE, PETITIONER,

v.

FLORIDA CITRUS EXCHANGE, FRANK R. SCHELL, ET AL.

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ON WRIT OF CERTIORARI TO THE UNITED STATES COURT  
OF APPEALS FOR THE FIFTH CIRCUIT

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## BRIEF FOR THE PETITIONER

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### OPINIONS BELOW

The opinions in the Court of Appeals are reported at 246 F. 2d 850. (R. 168-191). The Secretary's order (R. 158) appears in 20 F.R. 8493.

### JURISDICTION

The judgments of the Court of Appeals were entered on July 12, 1957 (R. 191-192). A motion for rehearing before the court *en banc* was denied on August 28, 1957, Chief Judge Hutcheson dissenting (R. 192). On November 27, 1957, by order of Justice Black, the time for filing a petition for a writ of certiorari was extended to and including January 3, 1958 (R. 260). The petition for a writ of certiorari was filed on January 3,

1958, and was granted on March 17, 1958 (R. 260). The jurisdiction of this Court rests on 28 U.S.C. 1254 (1) and Section 701(f)(4) of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 52 Stat. 1040, 1056, 21 U.S.C. 371(f)(4).

QUESTIONS PRESENTED

1. Whether the court below erred in directing the Secretary of Health, Education, and Welfare to certify as harmless for use in the coloring of oranges a coal-tar color which admittedly has been properly found to be poisonous and properly decertified for general use under Section 406(b) of the Federal Food, Drug, and Cosmetic Act.
2. Whether the provisions of Section 406(a) authorizing the Secretary to establish tolerances for use of poisonous substances in food, when required in production, applies to coal-tar colors found not to be harmless under Section 406(b).
3. Whether "required in the production," as used in Section 406(a), means required in post-harvest treatment of oranges for greater eye-appeal in the market place.
4. Whether, assuming that the Secretary has power to establish tolerances for use of poisonous coal-tar color on oranges, it was proper for the Court of Appeals to assume that *prima facie* the coloring for oranges was required in production, and not dangerous in that particular use, and thus to cast the burden on the Secretary to show that the use was dangerous to the health of man before he could remove the coal-tar color from the list of approved colors.

**STATUTE INVOLVED**

The Federal Food, Drug, and Cosmetic Act, as amended, 52 Stat. 1040; 70 Stat. 512 (21 U.S.C. 301 *et seq.*), provided in pertinent part as follows:

Sec: 402. A food shall be deemed to be adulterated—

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; \* \* \*

\* \* \* \* \*

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406 \* \* \* *Provided further*, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as "packing house elimination") the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as FD&C Red 32, or certified after such enactment as External D&C Red 14 in accordance with section 21, Code of Federal Regulations, part 9: *And pro-*

vided further, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406 [21 U.S.C., Supp. V, 342].

Sec. 406 (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). \* \* \* In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents [21 U.S.C. 346].

Sec. 701 (f) (1). In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States Court of Appeals for the circuit wherein such person resides or has <sup>his</sup> principal place of business, for a judicial review of such order \* \* \*.

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. \* \* \* The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari \* \* \* [21 U.S.C. 371].

#### STATEMENT

The Secretary of Health, Education, and Welfare, after public proceedings and on the basis of uncontested evidence, issued a final order on November 10, 1955, removing coal-tar colors<sup>1</sup> FD&C Orange No. 1, Orange No. 2, and Red No. 32 from the approved list

<sup>1</sup> "Coal-tar colors" are synthetic dyes, derived actually or theoretically from coal tar, which are widely used in coloring many foods, drugs, and cosmetics, 21 C.F.R. § 9.1, 20 F.R. 9554 (Dec. 20, 1955). "Coal tar" is the brown or black viscous liquid produced in connection with the destructive distillation of coal (Encyclopedia of Chemical Technology, Vol. 13, p. 614 (1954)). Coal tar is a by-product of coke production.

of harmless colors for unrestricted use in food, drugs, and cosmetics (R. 158.)

This rule-making order was reviewed generally and upheld by the Second Circuit in *Certified Color Industry Committee v. Secretary of Health, Education, and Welfare*, 236 F.2d 866. It was reviewed and held invalid, insofar as it concerns Red No. 32 as used for coloring oranges in Texas and Florida, by the court below in this case (R. 168-191). 246 F. 2d 850.

#### *A: The Secretary's Order:*

1. Red 32 had been placed on the approved list for use in food, drugs, and cosmetics in 1939, after a public hearing at which its harmlessness was apparently established. 4 F.R. 3931, 3936 (Finding 34). New investigations by the Department of Health, Education, and Welfare were initiated after scientific questions as to the possible carcinogenicity of Red 32 and other coal-tar colors had been raised. These investigations were spurred by the Hearings before a Select Committee of the House of Representatives to Investigate the use of Chemicals in Food Products.<sup>2</sup> The investigations, conducted with small laboratory animals (rats and dogs) which could be kept under careful observation during their life-time and sacrificed for careful post-mortem examination, were begun in 1951 and completed in 1953 (R. 206-209, 217, 219, 220-221, 241-252, 254-259). The result established to the satisfaction of

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<sup>2</sup> See the opinion below, R. 172, 246 F.2d 850, 853; *Certified Color Industry Committee v. Secretary*, 236 F.2d 866, 867 (C.A. 2), Hearings, Select Committee, 81st Cong., 2d Sess. (pursuant to H. Res. 323), pp. 229, 238; 82d Cong., 1st Sess. (pursuant to H. Res. 74), part 1, pp. 325, 326, 332, 334; 2d Sess. (pursuant to H. Res. 74 and 447), part 3, pp. 1353-1355, 1360, 1363, 1369, 1381.

trained toxicologists that the three colors involved in the instant order (Red 32, Orange 1, and Orange 2), have significant toxicity.

Upon completion of the investigations, the results were given to the certified color industry (R. 226), and the Department announced that a hearing would be held with a view to removing Red 32 and the other two colors from the list of harmless colors. At the hearing, the sole scientific witness for the color industry stated that the industry had no pharmacological data of its own to present, that the industry had done no such work since 1939, and that it was "willing to accept the result of the studies made by the Food and Drug Administration" (R. 226-228). The Florida Citrus Commission also indicated that it did not oppose "any action which the Secretary may deem advisable on the basis of the record" (R. 224).

Of the scientific investigations, the court below said: "The Secretary found that Red 32 is toxic; in other words that it is poisonous. The evidence justified the finding." R. 182, 246 F. 2d at 859.<sup>3</sup> The Secretary's detailed findings of fact reveal that Red 32 is the most toxic of the three colors. Pharmacological studies established that at 0.5% and 0.25% in the diet of test rats (5,000 to 2,500 parts per million (ppm)) the color killed most of the rats in a short time (R. 242). 0.1% (1,000 ppm) had the same, but a less rapid, effect (R.

<sup>3</sup> The Second Circuit, in evaluating the record, held that the overwhelming weight of the evidence had shown that the three colors might render food in which they were used injurious to health. It pointed out that the least toxic of the three had serious immediate effect on man and that the overall effect on the laboratory animals by proof on autopsy was alarming. "Consequently", it said, "the delisted colors are not 'harmless' within the meaning of Section 406(b)." 236 F. 2d 866, at 870.

242). On autopsy, the animals had liver damage, anemia, and enlargement of the right side of the heart<sup>4</sup> (R. 242-243, 246-249, 250-251). In dogs, 0.04% (400 ppm) caused deterioration, weight loss, sporadic diarrhea, moderate atrophy of vital organs and muscular dystrophic changes (R. 255-259). One dog at 0.01% (100 ppm), the lowest test dosage fed, lost weight and died (R. 254). A single oral dose of 100 milligrams (about 1/3 the weight of an ordinary 5 grain aspirin tablet) produced diarrhea (R. 259). (R. 158, 163, Findings 7-8).

The Secretary found the evidence inadequate to support findings as to the amounts of color likely to be ingested by man from his food, drugs, and cosmetics (R. 164, Finding 10). The industry committee representative testified that his company (one of the largest in the business) had done no work to learn how much of these colors is found on various foods, including oranges and products made from orange peel (R. 228). The Florida Citrus Commission did, however, present analyses based on samples drawn from "two boxes of color-added pineapple oranges" (R. 225).

The Secretary concluded both (1) that he had no statutory authority under Section 406(b) of the Federal Food, Drug and Cosmetic Act to list colors of established toxicity and then attempt by regulation to restrict the levels of use of these poisonous colors in selected foods, drugs, and cosmetics as a means of protecting the public from the consumption of harmful amounts of the toxic colors; and (2) that no safe level

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<sup>4</sup> No heart damage was found in rats fed 0.25% (2,500 ppm); yet at 0.1% (1,000 ppm) heart damage was definitely shown. The pathologist remarked on the fact of the lower dosage "showing a constant effect of the dye feeding on the heart" (R. 250-251).

of administration was found, even in test animals, for Red 32<sup>8</sup> (R. 164-165; Conclusions 1-2).

2. Petitions asking the Secretary to reopen the hearing were made by the Certified Color Industry Committee (R. 152), and Frank R. Schell (R. 116). Their purpose was to offer evidence to establish that the amounts of the three colors normally used in a variety of foods and drugs were substantially less than the lowest level of internal administration that caused damage to test animals (R. 152). More particularly, respondent Schell offered to prove that Red 32 is not dangerous to human health since there has been no evidence of injury to industrial workers in frequent contact with the color, and that the animal feeding tests in the record were of no significance because the amounts fed were far in excess of the amounts of color man would get from color-added oranges (R. 118-119). The aim was to show that the amounts of color normally used are wholly insignificant from a toxicological standpoint, and at least that safe tolerances could be established for the three colors in a number of foods and drugs, including oranges.

The Secretary refused to reopen (R. 154-157). His reasons were that the animal data failed to establish a safe level of dosage for Red 32 for the test animals; that man is more susceptible than the test animals, making it impossible to transpose the animal data directly to man; and that Red 32 had been involved in a recent food-poisoning episode, establishing the possibility that dangerous amounts would be used. The Secretary found the normal use data submitted in the

<sup>8</sup> A safe level of dosage to test animals would be an essential prerequisite to the establishment of a safe tolerance for man.

petitions to reopen to be inaccurate and incomplete, the pharmacological testing inadequate to establish the extent of toxicity to a certainty that would permit him to fix safe tolerances, and that there was no statutory authority on which he could issue regulations establishing tolerances for toxic coal-tar colors. He found also that the tests in the record are the tests customarily employed by competent toxicologists to determine the harmlessness of a substance; and that so far as is known no data exists which in any way contradicts the results of the studies shown in the record.

#### B. *Temporary Legislation:*

Before the administrative process had been completed, steps were taken in the Congress to enact legislation to keep Red 32 on the approved list for coloring oranges. After the tentative administrative order issued, a bill was introduced into the 84th Congress, H.R. 7732, to require the Secretary to continue the certification of Red 32 for coloring oranges until a color that is "more acceptable" (less toxic) should be "listed and made available for use." Hearings were held before the House Committee on Interstate and Foreign Commerce on February 10, 1956, a few days after the present cases were filed in the Court of Appeals for the Fifth Circuit. The Department of Health, Education, and Welfare opposed the bill. It proposed a temporary compromise to continue Red 32 on the list for coloring certain oranges for a period of not to exceed 3 years. This, it explained, was to allow time "for the development of a color that is not toxic," "for further exploration of the toxicity of FD&C Red 32", and "for further congressional consideration if a new color should not be found, and if it should be

necessary to amend the law to authorize the Department to prescribe a tolerance for Red 32 on oranges and impose other conditions to safeguard public health." In doing this, the Department explained that it had no positive proof that this temporary use would involve a likelihood of injury, but neither was there evidence available to establish that this use was wholly safe. The Department said that it could not agree to H.R. 7732, which would require the indefinite listing of Red 32 for oranges "before its safety for the purpose has been finally established" (Hearings, House Committee on Interstate and Foreign Commerce on H.R. 7732, 84th Cong., 2d Sess., pp. 2-3).

Both the House and Senate Committees adopted the Department's recommendations, but both made it clear that this temporary legislation was not intended to affect the outcome of the judicial review proceedings then under way in New York, Chicago, and New Orleans (*infra*, pp. 12-14). H. Rep. 1982, 84th Cong., 2d Sess., p. 3, and S. Rep. 2391, 84th Cong., 2d Sess., pp. 2-3.

The result of this Congressional consideration was Public Law 672, 84th Cong., 2d Sess., enacted July 9, 1956, 70 Stat. 512, under which the Florida and Texas orange growers were exempted from the prohibitions against Red 32 (now External D and C Red No. 14) until March 1, 1959.

Public Law 672 reads as follows:

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That paragraph (c) of section 402 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by inserting immediately*

before the period at the end thereof a colon and the following: "*Provided further*, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as 'packing house elimination'), the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as F.D. & C. Red 32, or certified after such enactment as External D. & C. Red 14 in accordance with section 21, Code of Federal Regulations, part 9: *And provided further*, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406."\*

### C. Litigation:

1. The Certified Color Industry Committee sought judicial review of the Secretary's order in the Court of Appeals for the Second Circuit. On August 10, 1956, that court affirmed the order, 236 F. 2d 866.

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\* There is pending in the 85th Congress H.R. 8945, a bill to authorize the Secretary to establish safe tolerances for coal-tar and other color additives. The Department of Health, Education, and Welfare reported on the bill on June 27, 1958, endorsing its principle, but asking for amendments which would provide clear authority and statutory guidance for limiting colors to particular foods and for fixing the maximum amounts of such colors as could be tolerated safely. The Secretary's report recognized that the present test of harmlessness is a stringent one, in the light of modern testing techniques, and asked the Congress for guidance as to changing the national policy with respect to tolerances for toxic coloring materials.

Eli Lilly thereupon dismissed its petition for judicial review in the Seventh Circuit.\*

The present cases were filed in the Fifth Circuit on February 2 and 8, 1956 (R. 2, 21) and were consolidated. On July 12, 1957, the Court of Appeals entered its judgment setting the order aside insofar as it removed Red 32 from the approved list of coal-tar colors that might be used on Texas and Florida oranges (R. 191-192). The court held that under existing law the Secretary had a duty to promulgate regulations establishing a safe tolerance and to continue the certification of Red 32 as a harmless coal-tar color for Texas and Florida oranges. This conclusion was reached by interpreting the word "harmless" in Section 406(b) as a relative term (R. 180-181, 183), and by reading Section 406(a) and 406(b) together to provide the needed statutory support for both a tolerance and the continued certification of Red 32 as a harmless coal-tar color for oranges.

The court said that Red 32 is an added poisonous substance (R. 182); that it is required in the production for market of oranges, because two Congressional Committees considering amendatory legislation found the practice of coloring oranges an economic necessity (R. 182); and that this usage is a safe one, because the Secretary (R. 180-181) and the Commissioner of Food and Drugs (R. 181, 186) have told the Congressional Committees that they know of no injury to man from color-added oranges. On this basis, the court reached its ultimate conclusion that "the 1939 finding should not be supplanted by a contrary ruling" "unless there is evidence that, in the amounts used, and in the man-

\* *Eli Lilly and Company v. Folsom, Secretary of Health, Education and Welfare* (C.A. 7, No. 11,682, January 16, 1957).

ner of use, oranges colored with Red 32 are unsafe for human consumption" (R. 186). While the Secretary is left free to make "further investigations" and to conduct hearings to decide whether he should or could promulgate a safe tolerance for Red 32 on oranges (R. 186-187), he is ordered to continue to certify the color as a safe one for this use on oranges without such a tolerance.

SUMMARY OF ARGUMENT

I

Under Sections 402(c) and 406(b) of the Federal Food, Drug, and Cosmetic Act (*supra*, pp. 3-4), Red 32—a toxic coal-tar—cannot be listed or certified as a harmless coal-tar color for use on any food in any amount.

- A. The Secretary's undisputed findings, based on uncontroverted scientific investigations, establish that Red 32 is a toxic or poisonous coal-tar color.
- B. The Act, which requires a certified coal-tar color to be "harmless," does not permit a toxic color such as Red 32 to be certified for any food use at all.
  - 1. Congress used the word "harmless" in Section 406(b) without qualification to mean those coal-tar colors that have been demonstrated to be without adverse physiological effect and technically suitable for any use in food; in other words, colors that are wholly innocuous. The statute provides for the certification of the color as such, not for any particular use of the color on any particular article or in any particular amount. Either the color is safe for use without limitation or regulation, or it is unsafe and may not be used at all. There is nothing in Section 406(b) or Section 402(c) which suggests that the Secretary has a duty to

retain on the list of harmless colors any color that is toxic, but which might possibly be used in safe amounts on a particular product.

2. The Court of Appeals agreed that Red 32 is a poisonous and deleterious substance, but held that the Secretary had the duty to keep it on his harmless list and make it available to orange growers until he was prepared to prove that this single use of the color would make the oranges dangerous to the health of man. The court read into Section 406(b), dealing specifically with coal-tar colors, the provisions of Section 406(a), *supra*, p. 4, permitting the use of poisonous substances *required in production of food*, under tolerances established by the Secretary. But the structure of the Act indicates that Congress did not consider Section 406(b) to be qualified in any way by Section 406(a). The two provisions deal with separate aspects of the problem of poisonous materials and develop different methods of handling. No provision was made for fixing tolerances as to toxic coal-tar colors. They were completely prohibited.

3. The legislative history of the Act strongly confirms the consistent administrative interpretation that toxic coal-tar colors were to be prohibited completely, and were not to be certified for particular uses on particular products. Congress was fully aware of the difference between coal-tar colors and those poisons necessary in production of foods, and as to the former deliberately adopted an all-or-nothing attitude.

## II

If Section 406(a) must be considered, despite our argument to the contrary in Point I, the court below misapplied it in expanding the statutory language "required in production" to include post-harvest treat-

ment of food to increase its acceptance in the market place by better coloration. "Required in production" means chemicals without which oranges cannot be brought to maturity, not post-harvest chemicals to promote salability. The expansive reading of the statute adopted below is contrary to the statute's basic aim to keep to an absolute minimum all poisonous and deleterious substances in our foods. Added poisonous and deleterious substances were banned without regard to whether the added substance might or might not render the treated food injurious. It was enough that the substance was a poisonous one. The only exception, for substances required in production or unavoidable, should be strictly construed to accomplish the evident purpose of the Act. A broad reading of the exception to cover poisons added for merchantability will open the national dietary to needless addition of poisons, and thus will have far-reaching consequences beyond the question of Red 32 for oranges. It will reverse national food policy which has been followed for years.

### III

Even assuming the correctness of the statutory interpretations of the court below, the Court of Appeals was clearly in error in presuming the safety of Red 32 when used on oranges, rather than remanding the case to the Secretary for further proceedings, with the burden on the proponents of the tolerance to adduce proof that the color is required in production and that a safe tolerance can be established for it.

There is now no adequate factual evidence to establish a safe level of feeding Red 32 to test animals, and thus no basis at all for forecasting what would be a safe

level of feeding for man. Even if authorized by present law, a safe tolerance for Red 32 on oranges cannot be drawn on the facts now known.

The lack of definitive proof of past injury to man cannot be used as a basis for continuing the use of the color on oranges. The purpose of the statute is to require proof that the practice will be safe, not to require the Secretary to prove that it will be dangerous. The public, and not the food dyes, should be given the benefit of any doubt. The burden is on the makers and users of the toxic coal-tar, not on the Secretary.

#### ARGUMENT

The Fifth Circuit below, despite its acceptance of the Secretary's finding on uncontroverted evidence that Red 32 is a toxic substance, has held that he must continue to certify it indefinitely as a harmless color for use on Texas and Florida oranges. Under the decision, the Secretary cannot, as to oranges, now supplant the initial 1939 finding that the color is a harmless one until he is prepared affirmatively to prove that the color on oranges would render the oranges themselves injurious to the health of man and unsafe for human consumption. The court holds that a "harmless" color is one that is relatively harmless, not absolutely harmless, and that a color is harmless in a relative sense if there is no evidence that it may render this single food—oranges—injurious to health if used on oranges alone. This result the court obtains by reading into Sections 402(c) and 406(b) of the Federal Food, Drug, and Cosmetic Act, dealing specifically with coal-tar colors, the tolerance provisions of Section 406(a) which provide that the Secretary may permit the adding of a poisonous or deleterious substance to food "where such sub-

stance is required in the production thereof or cannot be avoided by good manufacturing practice". Then the court goes still further to construe "required in the production thereof", as used in Section 406(a), as meaning required *for marketing* by a substantial segment of the orange-producing industry. And finally the court undertakes for itself to decide that the coloring of oranges is safe and casts upon the Secretary the burden to show that safe tolerances cannot be established.

We submit that the decision below is erroneous in all three aspects. As to coal-tar products, Congress has not given the Secretary any authority to permit any use on any food product of those coal-tars which are found to be toxic—and the finding that Red 32 is toxic is undisputed. Congress has decreed that toxic colors are not to be used at all on any food. Hence, the Secretary has no power under the statute to fix tolerances for use of Red 32 for oranges. But even assuming that he does, the decision below has misinterpreted Section 406(a) in holding that "required in the production" means "required in the production *for market*" by a particular industry. Finally, the court erred in itself making the requisite finding that coloring of oranges was required for production. Tolerances safe for oranges alone might not be safe if other products can also show that they need the use of coal-tar colors for production or marketing. The burden of showing lack of danger from an admitted poison should not rest on the Secretary but on the industry.

## I

Since Red 32 Is Poisonous, It Cannot, under the Federal Food, Drug, and Cosmetic Act, Be Listed or Certified as a Harmless Coal-Tar Color, or Used on Any Food in Any Amount

A. *The undisputed evidence establishes that Red 32 is a poison when ingested internally and cannot be classified as harmless.*

The court below held that there was adequate support for the Secretary's finding that Red 32 is a toxic color. There can be no doubt, on this record, as the Second Circuit has also held,<sup>1</sup> that the coloring materials as such are chemicals with demonstrated acute and chronic toxicity which may be used at levels which jeopardize the public health.

Findings 7-9 (R. 163-164), based on unchallenged scientific studies, detail the injuries to test animals clearly attributable to dye feeding. See the Statement, *supra*, pp. 6-8. While man cannot ordinarily be used as a test animal, the adverse effects produced in the laboratory on rats, dogs, and mice furnish material for assaying the toxic potential of color to be fed to man in his diet over a protracted period. Cf. *United States v. Wood*, 226 F. 2d 924, 927 (C.A. 4) and *United States v. Lesser*, 66 F. 2d 612 (C.A. 2). The only difference in response between man and test animals shown on this record is that, judged by the observable symptoms, man is somewhat more sensitive to Orange 1, the least toxic of the three colors involved in the administrative proceeding, than either the rat or the dog. And it is an accepted principle of the science of pharmacology that,

<sup>1</sup> *Certified Color Industry Committee v. Secretary*, 236 F. 2d 866.

on the basis of equal body weights, most animals are from five to ten times more resistant to a toxic agent than is man. *Procedures for the Appraisal of the Toxicity of Chemicals in Foods, Drugs, and Cosmetics*, 10 Food Drug Cosmetic Law Journal 679, 748 (Oct. 1955).

In considering the significance of the laboratory experiments, the expert agency had the practical problem of forecasting from the observed injuries to animals whether the colors would be deleterious to man. This was not too difficult, because adverse effects were produced by the lowest levels fed to both animal species tested, and, fortuitously, evidence as to man's response came from a poisoning episode with obvious symptoms —vomiting and diarrhea. Experience in the candy episode (R. 161, 163-164, Findings 4 and 9) and in the more recent popcorn poisoning (R. 155) has shown that Orange 1 and Red 32 can cause and have caused acute human poisoning.

B. *The statute, read as a whole and in the light of its history, excludes toxic coal-tar colors from listing and certification for any food use at all.*

As we read the statute, the undisputed factual finding that Red 32, a coal-tar color, is a substance dangerous to man—*i.e.*, it is *not* harmless—disposes of the issue in this case. Except for the special legislation permitting its use on oranges until March 1959 (*supra*, pp. 10-12), we believe that Congress has decreed that coal-tar colors which are not generally harmless and safe for unlimited use are not to be used in food at all.

1. *The terms of Sections 402(c) and 406(b) require certified coal-tar colors to be wholly harmless.*

The delegation to the Secretary by Section 406(b) of the Act (*supra*, p. 4) is plain and direct in its terms. He is told to—

\* \* \* promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.

Similarly, Section 402(c) (*supra*, p. 3) provides in absolute terms that a food shall be deemed adulterated "If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406."

This language embodies an all-or-nothing attitude toward coal-tar colors. Under the statutory scheme, the Secretary is directed to list and certify batches of harmless coal-tar colors suitable for use in foods, drugs, and cosmetics. If a color is from a certified batch, *any* food containing it is not adulterated; if the color is from an uncertified batch, *any* food containing it is adulterated. In other words, the coloring is either generally safe for use without limitation or it cannot be used at all.

The coal-tar color must be "harmless" before it can be certified. "Harmless" is a well-understood word which means "free from harm or the power to harm."<sup>8</sup>

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<sup>8</sup> The following definitions appear in standard dictionaries:

*Webster's New Collegiate Dictionary*, page 376:

"harmless—(1) Free from harm, liability, or loss. (2)

"Harmless", when unqualified, does not mean relatively free from harm, or only moderately harmful, or non-injurious for certain uses. It means "innocuous". There is no qualification in the statute which justifies the court below in reading "harmless" as "relatively harmless" in relation to a particular use on a particular product. Nor is any provision made for individual certification for a particular use or a particular product or for particular amounts.

Had Congress intended any qualification on the word "harmless," the language was readily at hand. Yet it made no qualification. Authority for so reading "harmless" was found by the court below in *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, and *W. B. Wood Mfy. Co. v. United States*, 286 Fed.

Free from power to harm; inoffensive; innocuous."

*Webster's New International Dictionary*, page 1139:

"harmless—(1) Free from harm; unhurt; free from liability or loss; as a bond to save one harmless. (2) Free from power or disposition to harm; inoffensive."

*Funk & Wagnalls New Standard Dictionary*, page 1117:

"harmless—(1) Having no power, tendency, or inclination to injure; innoxious; as, a harmless scheme; a harmless drug. (2) Without hurt, loss, or liability; uninjured; as, to escape harmless; to give bond to save another harmless."

*The New Century Dictionary*, page 715:

"harmless—Free from harm, unharmed, or uninjured (now rare); free from liability or loss (as to hold or save one harmless, as by the terms of an agreement); also, having done no harm, or innocent (archaic); now, commonly, destitute of power or tendency to harm; innocuous; inoffensive."

84 (C.A. 7) (R. 180). But "harmless" was not a part of the statute involved in those cases; rather, the statutory language was that food would be regarded as adulterated if it bears or contains an "added poisonous or other added deleterious ingredient which may render such article [food] *injurious to health.*" (Emphasis added.) Moreover, Congress added the new provisions of Section 406(b) to the Act when it was revised comprehensively in 1938 with the very purpose of overcoming the effect of the *Wood* decision (see *infra*, pp. 30 *et seq.*).

It is significant that the statute provides for certification of the color, as such, not for any particular use of the color, and without reference to amounts. Certification means to attest authoritatively—in this case, to declare officially that each production batch of Red 32 is a harmless coal-tar color. Certification to this fact is made on the basis of the examination of samples of the color in the laboratories of the Food and Drug Administration. 21 C.F.R. Part 9. Once the Secretary's stamp of approval is put on a batch of color, any manufacturer using the certified color in his food, drug, or cosmetic is officially assured of the color's harmlessness. He may use the color to achieve any tinctorial hue he desires and in any amount. Certification after careful laboratory analysis of a batch of color would be a pointless procedure if the product certified as harmless is instead an active poison which can cause harm if ingested in sufficient quantities. Such certification would do little or nothing to protect the public health, and might indeed have the opposite effect. Congress adopted the certification plan to make it unnecessary to examine colored foods to assure safety. It took no chances, and excluded from foods

all but certified harmless colors. This enables the Department of Health, Education, and Welfare to protect the public from unsafe coloring matter in food by simply refusing to certify any color that is not itself wholly harmless.\*

*2. Section 406(a), with its provision for tolerances, is inapplicable to coal-tar colors.*

As support for its holding that the statute permits the particular use of a coal-tar color which cannot be certified as wholly harmless, the court below turned to Section 406(a), *supra*, p. 4, which deals with a different subject (added poisonous and added deleterious substances required in the production of food) and provides a different system of control (the enforcement of tolerances established by regulations, not the certification of batches of coal-tar color). But Section 406(a) is inapplicable to coal-tar colors.

In Section 406(a), Congress recognized that there may be instances in which poisonous or deleterious ingredients should be permitted in food. It enacted a single exception to the flat prohibition against added poisons in food. That exception applied only to substances "required in the production thereof or [which] cannot be avoided by good manufacturing practice." And the Congress directed the Secretary (1) to establish tolerances for such required or unavoidable substances, limiting the quantity therein or thereon to such extent as necessary to protect the public health; (2) to "take into account the extent to which the use of such sub-

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\* Plainly, the color industry has so understood the plan of control. It has treated the colors, once certified, as wholly innocuous, and by the admission of the industry committee spokesman at the hearing has made no effort to learn how much color was being used in a variety of foods (R. 228).

stance is required or cannot be avoided in the production of each" article on which the poison is tolerated; and (3) to consider "the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances."

Yet in the very next paragraph—Section 406(b)—Congress authorized the promulgation of regulations to provide for listing and certification of "harmless" coal-tar colors. Plainly, the language was neither inadvertent nor meaningless. A coal-tar color could not be at once a poisonous substance controlled by paragraph (a) and a harmless color controlled by paragraph (b). Congress excluded poisonous coal-tar colors from paragraph (a) altogether, and pointedly said not a word in paragraph (b) about tolerances for coal-tar colors as a means of transposing a toxic substance into a "harmless" one. The two paragraphs were arranged to deal with two related, but different, subjects. While tolerances were authorized by Section 406(a) for added poisonous and deleterious substances required in production or unavoidable in good manufacturing practice, Section 406(b), immediately following and relating specifically and solely to coal-tar colors, uses the unqualified words "harmless and suitable for use in food." It says nothing at all about tolerances.

Congress must have recognized that coal-tar colors—which are manufactured to be added to foods, drugs and cosmetics for eye appeal alone—are not *required* in the production of such articles and can be avoided. It, therefore, provided for a list of harmless coal-tar colors that could be used without proof of necessity. To provide for tolerances for toxic coal-tar colors would run counter to the basic spirit of the Act, so strongly expressed in Section 406(a), to prevent the

use of poisons in food except where absolutely necessary or carefully controlled.

It seems clear that the Secretary was quite correct when he said in this case (R. 156) :

No standard or criteria have been established by the Congress whereby the Secretary may tolerate small amounts of poisonous colors in food, drugs or cosmetics. \* \* \*

\* \* \* the Federal Food, Drug, and Cosmetic Act does not establish a standard or guide by which the Secretary could select some products, and exclude others, in allowing use of small amounts of coal-tar colors which are toxic. The only method by which such a result could be reached would be arbitrarily to state that the color or colors would be limited to some foods, drugs, or cosmetics and not to others.

The Secretary could not borrow the criteria from Section 406(a), because toxic colors are neither required in production nor unavoidable in good manufacturing practice. And he dared not embark on a tolerance program without statutory guide lines, for to do so would open the Nation's food supply to unnecessary and avoidable poisons in defiance of the flat prohibitions of both Section 406(a) and (b). Perhaps tolerances should be established for coloring, under adequate guides, as the Secretary has agreed with respect to pending legislation (see the Statement, *supra*, p. 12, fn. 6). But that is for Congress to decide. Under the statute as it now stands, no such provision is made. The Secretary is merely directed to certify colors as wholly harmless; he is not given authority to certify them for use in particular quantities as to particular

foods. Up until now, the Congressional attitude has been that, if coal-tar colors <sup>are</sup> not wholly safe, they shall not be used in food at all. And this is a very significant choice of policy; under the present statute, which has no guidelines, if a color must be certified as not harmless in a particular use, such as oranges, it would presumably also have to be certified as not harmless in other particular uses, such as margarine. Even if each separate use alone would be safe, the total amount of color added to the totality of foods could well result in injury to health. Congress has thus far avoided that possibility by a flat prohibition on the use of toxic coal-tar colors.

*3. The legislative history and background of the statute show that Congress intended to prohibit listing or certification of toxic coal-tar colors for any purpose or use.*

Prior to 1938, Congress dealt with "added poisonous and other added deleterious substances in food", but not specifically with coal-tar colors. Section 7 of the original Pure Food and Drugs Act provided (34 Stat. 769) that food shall be deemed adulterated—

If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health \* \* \*.

This Court in *United States v. Lexington Mill and Elevator Co.*, 232 U.S. 399, 411, construed that section to give it comprehensive meaning. The Court said:

It is not required that the article of food containing added poisonous or other added deleterious ingredients must affect the public health, and it is not

incumbent upon the Government in order to make out a case to establish that fact. The act has placed upon the Government the burden of establishing \* \* \* that the added poisonous or deleterious substances must be such as may render such article injurious to health. The word "may" is here used in its ordinary and usual signification. \* \* \* In thus describing the offense Congress doubtless took into consideration that flour may be used in many ways, in bread, cake, gravy, broth, etc. It may be consumed, when prepared as a food, by the strong and the weak, the old and the young, the well and the sick; and it is intended that if any flour, because of any added poisonous or other deleterious ingredient, may possibly injure the health of any of these, it shall come within the ban of the statute. If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act. This is the plain meaning of the words \* \* \*.

In accord with this broad scope of the law, the administrators of the Act early initiated a voluntary system of certification for coal-tar colors. This system was the product of one of the most comprehensive investigations ever undertaken by the old Bureau of Chemistry, then charged with administration of the food and drug law. The Department of Agriculture employed an outside expert on coal-tar colors, Dr. Berhard C. Hesse, to develop the system. Dr. Hesse's monumental work, Bureau of Chemistry Bulletin No. 147, was issued in February 1912. In transmitting it to

the Secretary of Agriculture, Dr. Harvey W. Wiley stated that the data developed by Dr. Hesse formed the basis for Food Inspection Decisions 76, 77 and 106. Much of the Bulletin was devoted to the "harmfulness of coal-tar colors and their physiological effects." After reviewing all the existing scientific literature, the laws of foreign countries, the recommendations of producers and users of coal-tar colors, the Bulletin recommended that only 7 colors be permitted in foods. The rules governing the selection of the colors were (pp. 161-162 of the Bulletin) :

- Rule I. All colors which have not been physiologically tested either upon animals or man shall not be permitted for use in foods.
- Rule II. All coal-tar colors which have been examined physiologically with contradictory results shall not be permitted for use in foods.
- Rule III. All coal-tar colors which have been examined physiologically and have been declared to be of doubtful harmlessness shall not be permitted for use in foods.
- Rule IV. Only those coal-tar colors whose chemical composition was definitely disclosed or otherwise ascertained . . . and which have been examined physiologically and with no other than a favorable result shall, for the present, be permitted for use in foods.

These rules were evolved after a public hearing in New York City (Bulletin, pp. 47-51), at which several persons recommended that colors be allowed in food if

"harmless in the quantities employed." Calverv, *Coal-Tar Colors, Their Use in Food, Drugs, and Cosmetics*, 114 American Journal of Pharmacy, 326 (1942). But that idea was rejected, in favor of the position advocated by others who participated in the hearing—that the rules should permit only the colors "which have been proven to be entirely harmless, even if taken in large doses" (Bulletin, 51, 61-62).

Though it continued to employ this voluntary system, the Government found it virtually impossible to proceed in court against poisonous coal-tar colors in foods, primarily because of the difficulty of proving that the particular amount of the toxic color in the particular food "may render [the food] injurious to health." *W. B. Wood Manufacturing Co. v. United States*, 286 Fed. 84, 86 (C.A. 7), held that such proof was necessary.

Accordingly the Department of Agriculture recommended that Congress make the certification system mandatory and reverse the effect of the *Wood* case by describing as adulterated foods those bearing uncertified coal-tar colors.

Senator Copeland's memorandum on S. 1944, 73rd Cong.,<sup>10</sup> discussing the weaknesses of the original 1906 Pure Food and Drugs Act,<sup>11</sup> pointed out that that law had no provision prohibiting use of uncertified coal-tar colors in food, and that:

<sup>10</sup> Dunn, *Federal Food, Drug, and Cosmetic Act*, a Statement of its Legislative Record, pp. 30-31. This was the original bill which culminated in the 1938 revision. Senator Copeland, a medical doctor who had been a public health official of New York State, was the leading sponsor of the legislation throughout its entire 5 year course in Congress.

<sup>11</sup> 34 Stat. 768, c. 3915, Sections 1-11.

\* \* \* No action can be taken unless it can be proved that colors or their impurities are poisonous and that they are present in such quantities as may be harmful to health.

The purpose of the amendment providing for listing and certification of harmless coal-tar colors, he said, was to overcome the need which arose under the 1906 Act to prove that the colors or impurities were "present in such quantities as may be harmful to health." The voluntary system of certification was expressly called to the attention of the Congress. Describing it, the Senate Committee said (S. Rep. 361, 74th Cong., 1st Sess., 6-8 (1935); Dunn, *op. cit.*, p. 243):

As a matter of administrative practice in the Department of Agriculture, provision was made for the certification of coal-tar colors shortly after the enactment of the present law. Under this procedure those colors which were demonstrated to be without adverse physiological action, and which from a technical standpoint were suitable for use as food colors, were admitted for certification. Individual batches of these particular colors were then certified by the Department after examination which demonstrated their freedom from toxic impurities. This has resulted in an adequate supply of harmless colors for all food uses and has operated to the satisfaction of the industry. Nevertheless, uncertified colors such as paint pigments, many of which are distinctly harmful, have been used from time to time. \* \* \* \* legislative sanction

is given to the administrative practice of the Department in certifying colors.<sup>11</sup>

This explanation was drawn almost verbatim from the testimony of Walter G. Campbell, then Chief of the Food and Drug Administration. See Hearings before the Senate Committee on Commerce on S. 2800, 73d Cong., 2d Sess., p. 597; Dunn, *op. cit.*, pp. 1201-1202; and Hearings Before the Senate Committee on Commerce on S. 1944, 73d Cong., 1st Sess., p. 28.

Congress thus accepted the idea put forward by Mr. Campbell that the certification regulations should assure manufacturers and other purchasers "that the colors used by them would be nontoxic and free from deleterious ingredients." As the Senate Report already quoted (*supra*, pp. 31-32) put it (S. Rep. 361, 74th Cong., 1st Sess., p. 7; Dunn, *op. cit.*, p. 243):

Paragraph (c), prohibiting the use of any coal-tar color other than a certified color, is a precaution against the promiscuous use of coal-tar colors, the number of which is legion, and the most of which are toxic.

With respect to the present claim that tolerances can be established for these toxic coal-tar colors, it is significant that, throughout the legislative history, the provisions as to coal-tar colors are discussed separately from those with respect to tolerances. For example, in S. Rep. 361, 74th Cong. 1st Sess. 6-8, Dunn, *op. cit.* pp. 241-243, the Committee first discussed the ban on poisons with provision for tolerances and then discussed

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<sup>11</sup> These same ideas were expressed in reports on other bills, out of which finally came the Federal Food, Drug, and Cosmetic Act. S. Rep. 493, 73d Cong., 2d Sess., pp. 4-6, Dunn, *op. cit.*, at 113-114 (on S. 2800); H. Rep. 2139, 75th Cong., 3d Sess., p. 6, Dunn, *op. cit.*, at 820.

the provision against "the use of any coal-tar color other than a certified color." And it is also indicative of the Congressional understanding that such tolerances could *not* be fixed for coal-tar colors on particular foods. An attempt was at one time made to make special provision for the coloring of oranges. At one point early in the legislative development of the Federal Food, Drug, and Cosmetic Act, a provision was inserted in S. 2800 to guarantee the continued availability of coloring for citrus fruit. This proviso said:

Sec. 3(e). Nothing in this Act shall be construed to prohibit the enhancement of the color of mature and wholesome citrus fruits to the varietal color thereof, by means harmless to the consumer of such fruits, nor to require any declaration of such enhancement, by labeling or otherwise.

S. 2800, 73d Cong., as amended by the Senate Committee on Commerce, 78 Cong. Rec. 4567; Dunn, *op. cit.*, at pp. 167, 169. That proviso would have been unnecessary if Congress had contemplated the fixing of tolerances for coal-tar colors under the equivalent of present Section 406(a). But while Section 406(a) appears in substance in all the subsequent bills, the proviso as to oranges did not reappear in the bills either in the 74th Congress or the 75th Congress, S. 5, 74th Cong., Dunn, *op. cit.*, at pp. 213, 216, 513, 533; and S. 5, 75th Cong., Dunn, *op. cit.*, pp. 633, 644. In its stead, a proviso emerged in the bill reported by the House Committee (Dunn, *op. cit.*, pp. 774, 800) which simply protected the citrus growers in the use of existing colors until applications for their listing as "harmless" colors could be acted on by the Department.

This legislative episode shows that Section 406(a), dealing with tolerances for necessary poisons, and Section 406(b), dealing specifically with coal-tar coloring, were considered as covering separate aspects of the problem of keeping food healthful. It did not appear to be the view of anyone, not even those anxious to preserve coloring for oranges, that coloring matter could be covered by the tolerance procedure authorized in Section 406(a) for poisons necessary for production of foods.

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We believe that this legislative history strongly confirms the Secretary's understanding of Section 406(b), *supra*, p. 4, which allows the listing and certification only of colors demonstrated to be without adverse physiological effect. Under this construction, colors which may readily be used in amounts that would injure man cannot be certified as harmless.<sup>12</sup> As we have shown,

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<sup>12</sup> At one point in the opinion below, the court said there was no need to pursue the inquiry whether there had been an administrative construction contrary to the one urged here (R. 177). Later, however, the court said that the Secretary at one time seemed to be of the opinion that he had the power to establish a tolerance for toxic colors and had done so with respect to certain "lakes" used on Easter eggs (R. 183-184). There is no record explanation of why the lakes were so restricted. The record in the hearing in 1939, on which the regulation was based, shows that toxicity of the lakes was not even involved. In fact, this restriction was made because the lakes produced "mottled shades of green, yellow, red [and] blue", so desirable on Easter eggs but wholly unacceptable in coloring other foods. Record, 1939 Hearing for \* \* \* Amending Regulations under the Federal Food, Drug, and Cosmetic Act for the Listing of Coal-Tar Colors, F.D.C. Docket 13, p. 40. The required label statement was to avoid consumer disappointment with the color, not to allow the sale of toxic dyes. Moreover, the Annual Report of the Food and Drug Administration for 1934, p. 6, contained the following discussion of coal-tar dyes used on Easter eggs:

"Another brief campaign of probable, public-health significance was undertaken just before Easter and resulted in removal from

there is not a hint of a suggestion that Congress intended the listing of toxic colors with tolerances to restrict the amounts of such colors that might be safely used in particular foods. Nothing could be clearer than that Congress did not intend, by the new language of Section 406(b) and 402(c), to accomplish only what had been the law under the original 1906 Act, as construed in the *Wood case, supra*, pp. 22, 30. Cf. *United States v. Walsh*, 331 U.S. 432, 436-437. The purpose of Congress was to make the former voluntary system mandatory, and to require the Department to list and certify only innocuous coal-tar colors, which could then be used by all food, drug, and cosmetic manufacturers without restraint as to quantity or commodity to achieve any desired tinctorial hue.<sup>13</sup>

## II

### **Even If the Standards of Section 406(a) of the Federal Food, Drug, and Cosmetic Act Are Applicable to Coal-Tar Colors, There Is No Proof That Coal-Tar Coloring Is Necessary for the Production of Oranges Within the Meaning of That Section**

As discussed above, pp. 19-35, we believe it was error to construe Section 406(a) as having any applicability at all to coal-tar colors. However, even if appli-

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the market of 16 consignments of Easter-egg dyes containing poisonous ingredients. The colors seized were essentially in the class of house paints, containing such toxic ingredients as cadmium sulphide, zinc sulphide, and barium sulphate with small percentages of lead as a contaminating impurity. Most egg dyes are harmless, and there is every reason to believe that these actions have put a stop to the distribution of poisonous products of this class."

This plainly shows that the Administration has been consistent in its insistence that coal-tar colors be harmless, regardless of the use.

<sup>13</sup> It goes without saying that the construction of Section 406(b) adopted by the court below goes contrary to the established administrative understanding and practice. See footnote 12, *supra*. E.g., *United States v. Allen-Bradley Co.*, 352 U.S. 306, 309.

cable, the section has been misapplied by the court below by equating "required in the production" with economic needs in merchantability, and by authorizing continued use of the color before the Secretary has taken the necessary steps to establish the tolerance.

A. *Section 406(a) was designed as a narrow exception to a flat prohibition against the use of poisons in food.*

The general philosophy of the Act, as it deals with poisonous substances, is apparent from Sections 402(a) and 406(a) *supra*, pp. 3-4. Section 402(a)(1) provides that a food shall not be deemed adulterated "If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an *added* substance such food shall not be considered adulterated \* \* \* if the quantity of such substance in such food does not *ordinarily* render it injurious to health \* \* \*." [Emphasis added.] Section 402(a)(2) provides that a food shall be deemed adulterated "if it bears or contains any *added* poisonous or deleterious substance which is unsafe within the meaning of section 406." [Emphasis added.] And section 406 declares all added poisonous or deleterious substances unsafe, unless required in production or unavoidable in good manufacturing practice. Section 406 then allows the Secretary to promulgate tolerances as to quantities of such *added* poisonous or deleterious substances when they can be safely permitted in a variety of foods.

Thus, even in regard to those poisonous substances which were not singled out for special treatment, as were coal-tar colors, the Act authorizes tolerances only where such substances are necessary or unavoidable.

The only poisonous substances allowed in food at levels which do not "ordinarily" render the food injurious to health are those which are not added, but are normally present as natural components of food, such as oxalic acid in spinach. The test applicable to naturally occurring poisonous substances was rejected both for added poisons and for "harmless" coal-tar colors. Rather, Congress established a strict general rule of exclusion against all poisonous and deleterious substances that might be added to foods. This was without regard to whether the added substances might or might not render the treated food injurious to health. It was enough that the added substance itself was a poisonous or deleterious one.

A single exception was made. When the added substance was required in the production of food or could not be avoided by good manufacturing practice, the Secretary was authorized to establish a tolerance for it, taking into account the extent to which the added substance was required or was unavoidable, the amount of the poison that might be safely tolerated, the extent to which the poison was required or unavoidable in this and other foods, and the other ways in which the consumer might be affected by the same or other poisonous or deleterious substances.

This was a new legislative approach to added poisons. As noted *supra*, pp. 27-28, this Court, in *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 409-411, had held that under the 1906 language a food was adulterated if it contained any added poisonous or deleterious ingredient which may possibly injure the health of any consumer, "the strong and the weak, the old and the young, the well and the sick." If the added substance in the food could not "by any possibility" injure the

health of any consumer, the small addition of poisonous or deleterious ingredients was not condemned. As strong as this prohibition was, it did not go far enough. Each food had to be considered alone, and there was no adulteration unless the particular food contained enough poison so that that food "may" be injurious to health. Small amounts of the same poison in a variety of common foods in the diet were beyond effective control.

The new provision in Section 406(a) was designed to arm the Department with power to establish tolerances for the entire variety of foods in which a common poison or related poisons were required or were unavoidable, and thereby to limit man's total intake of each such poison to a safe level.

This provision was advocated by Mr. Campbell for the Food and Drug Administration. He said, in discussing this provision of S. 2800, 73rd Congress, 2nd Sess.:

"... Control of added poisons in food and cosmetics is one of the most important provisions of the bill. It is impossible to eliminate entirely all added poisonous substances, but it is important that the amount the consumer ingests be kept to such a low limit that his total intake of the poisons will not impair his health. This can be done only by placing definite limitations on added poisons where they are unavoidable, as in the case of fruits and vegetables where spraying is essential to their production, and by prohibiting entirely the addition of poisons to foods where it is practicable to do this and where the added poison serves no genuinely useful purpose. In the present law it is necessary in a proceeding based on added poison to

show that the food in the particular shipment on which the proceeding is based contains added poison in such quantity as may impair the consumer's health. No account can be taken in such proceedings of the probable intake of the same or similar poisons from other sources. \* \* \*

\* \* \* In promulgating such tolerances this section requires that there be taken into account the extent to which the use of the poison is required in the production of the article and the other ways in which the consumer may be affected by the same or other poisonous substances. This will permit the establishment of comparatively liberal tolerances for any food where poison is unavoidable or is required by the necessity of production, and less liberal tolerances or complete prohibitions where it is practicable to limit the amount or to eliminate the poison completely. Such entire prohibition would be justified in those situations where irresponsible manufacturers, for some fanciful or real commercial advantage, add dangerously toxic substances to food as, for example, the addition of ethylene glycol to frozen eggs to promote "smoothness", or maleic acid to fats and oils to prevent rancidity when preservation can be accomplished by observance of sanitary conditions and by the use of refrigeration. In approaching the problem of control from this angle, the amount of added poisons can be so allocated to different foods, in accordance with the practical necessities, that on the basis of the probable consumption of various foods consumers will not receive an aggregate

quantity of poisons sufficient to jeopardize health.

\* \* \*

Hearings before the Senate Committee on Commerce, on S. 2800, 73d Cong., 2d Sess., pp. 596-597; Dunn, *op. cit.*, p. 1201.

Congress adopted this policy. It explained Section 406(a) [then Section 304(a)] of S. 5, 74th Cong.] as follows:

[This] prohibits the addition of poisonous or deleterious substances to food except where such addition is required in production, as in the case of poisonous sprays for fruits and vegetables to protect them against insects or fungus diseases, or where such addition cannot be avoided in good manufacturing practice, as where purification processes cannot entirely eliminate a contaminant of raw materials, or where some contaminant is unavoidably introduced in factory operations. This section then authorizes the establishment of tolerances for the protection of public health in those instances where the addition of the poison is required or cannot be avoided.\* \* \*

S. Rep. 361, 74th Cong., 1st Sess., pp. 6-8; Dunn, *op. cit.*, pp. 241-242. See also S. Rep. 493, 73d Cong., 2d Sess., pp. 4-6; Dunn, *op. cit.*, p. 113.<sup>14</sup>

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<sup>14</sup> S. Rep. 493 states:

"\* \* \* In promulgating such regulations this section requires that there be taken into account the extent to which the use of the poison is required in the production of the article, as for example, poisonous sprays in producing certain fruits and vegetables, and likewise, the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. This authorization will permit the establishment of comparatively liberal tolerances for any food where poison is unavoidable or is required by the necessities

In short, the basic attitude of Congress toward poisonous materials, as reflected in Section 406(a), is that they should not be added to food at all. The exception for tolerances to be fixed by the Secretary was intended to be limited to situations of real necessity—when the substance is “required in the production thereof or cannot be avoided by good manufacturing practice.”

*B. There is no record basis for a finding that Red 32 is “required in the production of” oranges.*

Considering the very narrow scope of the exception created by Congress in Section 406(a), it is inconsistent with its purpose to construe the section's words “required in the production”, as the court below has construed them, as meaning “required for marketability.”

The hearing before the Secretary was not at all concerned with the question whether Red 32 is “required in the production” of oranges.<sup>15</sup> Indeed, the Florida

of production, and less liberal tolerances or complete prohibitions where it is practicable to limit the amount of poison in a particular food to very small quantities, or to eliminate it completely. It will likewise afford adequate control of those situations where irresponsible manufacturers, for some fancied or real commercial advantage, add dangerously toxic substances to foods, as, for example, the addition of maleic acid to fats and oils to prevent rancidity when preservation can be accomplished by observance of sanitary conditions in manufacture and packaging and by use of refrigeration for the finished product.

“In approaching the problem of control from this angle the amount of added poisons can be so allocated to different foods, in accordance with the practical necessities, that on the basis of the probable consumption of the various foods consumers will not receive an aggregate quantity of poisons sufficient to jeopardize health. \* \* \*

<sup>15</sup> The Secretary's order should stand or fall on whether he fairly dealt with the whole issue before him, i.e., the harmlessness of

Citrus Commission's witness said that the Commission did not oppose any action the Secretary might deem advisable on the basis of the record (R. 224). And the motions to reopen did not offer any proof on the point. Respondent Schell wanted to prove that there was a sinister motive behind the proceeding (R. 117-118), and that no possible harm could come from the consumption of color-added oranges (R. 118-119). The Color Industry motion offered to prove that under "normal conditions of use" the three colors would be classified as harmless (R. 152-153). The idea of tolerances under Section 406(a) was mentioned only briefly in respondent Schell's brief (R. 138), but was not pressed until the case reached the Court of Appeals.

There, after holding that Section 406(a) should apply, the court found that Red 32 had been described as an economic necessity by two Congressional Committees, and thus that it is "required in the production for market of oranges grown by a substantial segment of the orange producing industry" (R. 175, 182-183). It held also that the Secretary need not consider other uses of Red 32, since even though there was no express provision permitting him to do so, neither was there a prohibition in the statute against his limiting the color to this single use (R. 183).<sup>16</sup>

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Red 32 when listed for unrestricted use in foods, drugs, and cosmetics. The court below agreed with his handling of this broad question, but said he could not take Red 32 away from the orange growers. A rule of general applicability should not be set aside simply because it works a hardship on some who are affected by it. In *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, a wholesome product with a commercial history had to be withdrawn from the market because the regulations fairly established standards for related foods.

<sup>16</sup> While the court limited its judgment to Red 32 on mature oranges, it said: "If there be other like situations, then of course that which we hold will be applicable to them" (R. 179).

"Required in production" of oranges, we believe, means substances required in growing the fruit, not post-harvest treatment of the food to promote its attractiveness in the market place. In the first place, this is what Mr. Campbell and the Congressional Committees thought the phrase meant. *Supra*, pp. 38-41.<sup>17</sup> Second, "production" does not normally include marketing. Third, "required", in the context of this statute (cf. *Armour & Co. v. Wantock*, 323 U. S. 126, 129-130), is not to be given an expansive meaning so as to include poisons in the food supply. Rather, it should limit the number to those poisons which can meet the rigid standards established by Congress. It must be read narrowly as part of an exception to the general rule of blanket exclusion of poisons, and not to cover toxic substances which might be added for some "fancied or real commercial advantage."

Should this court sustain the holding below, it would, of course, have far reaching significance beyond Red 32 as used on oranges. Such an interpretation would apply not to oranges alone, but to all foods in which a toxic substance might contribute something to salability. It would reverse a long standing Departmental policy which has excluded from foods such substances as poisonous artificial sweeteners, 21 C. F. R. 3.14, coumarin, 21 C.F.R. 3.33, and quarternary ammonium compounds, 21 C.F.R., 1958 Cum. Supp., 3.203. In May 1957, the Department published an order removing yellow colors, used principally in margarine, from the list of colors available for unrestricted use in

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<sup>17</sup> H.R. Rep. 2139, 75th Cong., 3d Sess., p. 6, Dunn, *op. cit.*, 815, 820, said: "It is well recognized that an adequate fruit and vegetable supply could not be brought to maturity without the use of toxic insecticides and fungicides."

food, drugs, and cosmetics, 22 F.R. 3173. Coloring is probably as important a factor in the marketing of margarine as it is in the marketing of oranges. If, despite our argument in Point I, tolerances are to be applied to coal-tar colors, and the test of necessity for such a tolerance is to be the use of the color in promoting marketability, it is obvious that much more than oranges will be affected by the decision below.

But the basic fact is, as we have shown, that the test of marketability has not been established by Congress. Congress has decided as a temporary measure that, until March 1959, coloring may be used on oranges alone. *Supra*, pp. 11-12. If Congress desires to continue that exception, it can do so. But a rule laid down by this Court in favor of respondents would be a general interpretation which could affect, beyond 1959, not only coal-tar colors, but the standards to be applied to determining whether tolerances should be allowed under Section 406(a) as to all kinds of poisonous substances. Such an interpretation would be clearly incompatible with the statutory language of Section 406(a)—“required in the production thereof”—even if that section is to be applied to coal-tar coloring.

### III

#### **The Court Below Was Not Justified in Making Its Own Finding That Coloring for Oranges Is Required for Production and Casting on the Secretary the Burden to Show That Safe Tolerances Cannot Be Established**

Section 406(a) provides for the use of a dangerous substance in food in accordance with tolerances fixed by the Secretary after consideration, not only of the necessity for its use “in the production of” a particular food, but also of the degree of danger represented by the use of similar substances in other foods. Hence,

even assuming the correctness of the statutory interpretations by the court below, it erred in itself making the requisite finding that coloring of oranges was required for production (including marketing) and casting the burden on the Secretary to show that safe tolerances cannot be established. As pointed out above, at pp. 26-27, 39-40, 43-44, tolerances safe for oranges alone might not be safe if, under the interpretation of the court below, other products can also show that they should be allowed to use coal-tar colors because required in their production or marketing. On this record, the court below was not justified in presuming that proper tolerances could be established.

*A. The facts needed to establish a safe tolerance for Red 32 on oranges do not exist.*

Actually, there is on this record no proof that the use of Red 32 on oranges alone is safe, much less proof that safe tolerances for general use can be established. The sole support for the view that the use of Red 32 on oranges is safe comes from outside the record—from statements made by the Department of Health, Education and Welfare in commenting on the temporary legislation (legislation the opinion below renders unnecessary).<sup>18</sup> The court below takes the Secretary's "guarded statement"—that on the evidence so far available there has been no established likelihood of injury to man from eating color-added oranges—as an apparent concession that Red 32 on oranges would involve no hazard to health (R. 180). The safety of the

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<sup>18</sup> Hearings before a Subcommittee of the House Committee on Interstate and Foreign Commerce on H.R. 7732, 84th Cong., 2d Sess., pp. 2-3, 17-18.

practice is taken as a fact until there is proof that the quantities of Red 32 on oranges "are dangerous to public health" (R. 181). But a fair reading of what the Department representatives said gives no assurance that Red 32 is harmless when used solely for coloring oranges. Instead, the Department made it plain that the harmlessness of coloring oranges with Red 32 is not yet established, and will not be until further comprehensive animal studies are undertaken and completed. That was the very purpose of limiting the temporary legislation to a 3 year period. The portion of the Secretary's letter quoted in the opinion below (R. 184-185) makes this quite plain. Thus, it cannot be said with any real conviction that Red 32 is a harmless color even if it could lawfully be restricted to use solely on color-added oranges—which under the reasoning of the court below it could not be. And it most certainly is not a harmless color for unrestricted use in or on food (see Point I, A, *supra*, pp. 19-20).

The respondents argue that the animal proof of the toxicity of Red 32 was largely meaningless because the levels of color fed were not related specifically to the amounts of Red 32 man would likely obtain from color-added oranges.<sup>19</sup> They attempt to avoid the impact of the uncontradicted evidence, and the conclusive findings of fact, by showing that man would have to eat thousands of oranges each day to ingest an amount of

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<sup>19</sup> The argument is made that even table salt has an adverse physiological effect if taken in large enough amounts. The record shows that 2 or 3 ounces of salt would adversely affect man, but that is 56,869 to 85,048 milligrams, as compared with 100 milligrams of Red 32, the cathartic dose for dogs. The substances are in no real sense comparable. The only comparison shown on the record with a recognized poison is with carbolic acid (R. 220-221), and Red 32 is more toxic chronically than carbolic acid.

color comparable to that which killed and injured the test rats and dogs. The difficulty with such an analysis is that the comparisons drawn are based on levels of animal feedings which caused injury or death, not on levels which were safe for the test animals. Since no level of safe feeding for animals has yet been established by appropriate scientific study, and since 100 ppm (parts per million) in the diet of dogs, the lowest level fed, killed one of the dogs, there is simply no proper starting point for estimating a safe dose for man, and thus no factual basis for concluding that Red 32 on oranges is wholly without hazard.

The respondents, with no evidence in the record to support their claim of harmlessness, rely heavily on an analysis of the findings by a Dr. Gerwe, which was originally filed as a part of the exceptions to the proposed order (R. 112-115).<sup>20</sup> Dr. Gerwe's background has been in chemistry rather than pharmacology or toxicology. In his analysis, in the last paragraph, he states that "the feeding levels \* \* \* employed in the experiments are \* \* \* fantastically greater than the amounts or levels that a person might get by eating oranges or by

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<sup>20</sup> A much more reliable scientific appraisal of this entire problem is the one done by an *ad hoc* Advisory Committee of the National Academy of Sciences—National Research Council, appointed to review the Food and Drug Administration Research Program on Coal-Tar Dyes. The Committee's report of June 1956 (in mimeograph only) includes a section entitled "Review of Toxicology and Pharmacology Research Program", pp. 7-13. It found the decertification of the three dyes justified, and indicated that decertification of some others may be justifiable on the evidence available. While the Committee indicated that the concept of "harmless" is unrealistic if levels of use are not specified, it noted that manufacturers assume they may safely incorporate in their products any quantity of a certified dye. No suggestion was made to withdraw the decertification of Red 32.

drinking the juice." They were "fantastic" only if their purpose is misunderstood. They were designed for the purpose of determining whether the colors under consideration could be regarded as "harmless", as the word is understood by a qualified toxicologist. They were the tests customarily employed by competent toxicologists for that purpose. The tests were not directed to the question of whether the amount of this color currently used for any single food purpose might be safely tolerated under the limitations of strict regulations. They were conducted to enable the Department to reach a sound judgment on whether Red 32 can be regarded as a harmless color for unrestricted use in the Nation's dietary.

In paragraphs 3 and 4 of his analysis, Dr. Gerwe compares the amount of Red 32 fed the rats in one of the experiments with the amount of oranges a human being would have to eat to obtain a comparable amount of the color (R. 113). Aside from the fact that man is much more susceptible to the effects of the color than animals and would obtain quantities of this color from other sources than oranges unless there were some lawful way to restrict its use,<sup>21</sup> it serves no purpose to

<sup>21</sup> Exhibit 7 introduced at the hearing through Robert C. Evans, General Manager of the Florida Citrus Commission, has not been included in the printed record. It showed, however, that for the 1948-1949 season the weight of the colored oranges shipped from Florida that year was approximately one billion eight million pounds (based on a weight of 90 pounds per box of oranges). Louis Gardner MacDowell testified that the average amount of dye contained on whole oranges was approximately six parts per million. Assuming these oranges contained six parts per million of Red 32, that gives us approximately 11,000 pounds of this color which was used for coloring oranges, according to the respondents. This is the principal use for this color, yet the certification figures of the Food and Drug Administration show that for the past ten

compare one tenth of one per cent of the color which caused injury to rats with the amount of oranges a man would have to consume to be equally injured. At this level of consumption the color stunted the growth of rats, enlarged their hearts, and caused them to die. This was not a safe level of administration.

It was recognized both by the Secretary and by the court below that no safe level of feeding of Red 32 to test animals has yet been established. Congress enacted the temporary legislation—P.L. 672, 84th Cong., 2d Sess., 70 Stat. 512, *supra*, pp. 11-12, to allow time for the further exploration of the toxicity of Red 32. H. Rep. 1982, p. 3. Without evidence as to the precise toxic potential of Red 32 to test animals, there is no way to devise a safe tolerance for man.<sup>22</sup>

#### *B. The Secretary does not have the burden of showing danger.*

Instead of recognizing the absence of a safe level as an insuperable obstacle to the application of the tolerance provisions of Section 406(a), the court below forbade the Secretary to revoke his 1939 finding of the harmlessness of Red 32, until he acquired evidence to show that the color-added oranges would be dangerous to health. This means that the color on oranges is assumed to be safe until the contrary is proven. The burden is on the Secretary to prove danger.

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years the amounts of Red 32 certified have averaged 40,000 pounds. This leaves 29,000 pounds unaccounted for by the color estimated to be on the skin of oranges. (R. 155-156).

<sup>22</sup> The respondents asserted below that certain Canadian experiments had established a safe level for Red 32 at 300 ppm. But Canada followed the Secretary's example and took the three colors off its list on July 26, 1956. P.C. 1956-1148, revoking regulations B.06.025-027, Canada Gazette, SOR/56-271 (Vol. 90, Part 2, p. 800).

This interpretation is clearly erroneous. If Section 406(a) is held applicable at all, the burden should be on the respondents to come forward with proof of safety. A toxic color is not to be tolerated on the negative evidence that no known injury to man has yet occurred. On the contrary, it cannot be tolerated until there is positive proof of safety. We should not wait for positive injury to man, but should view the law as a measure to prevent injury. As one scientist at the hearing put it: "It is imperative that the public, and not the food dyes, be given the benefit of any doubt." (R. 223). Colors should not remain on the harmless list, and in food use, when there is a reasonable doubt as to their safety. The Secretary is surely authorized to take into consideration the "margin of safety which the public interest required" in making his forecasts as to the future safety of a coal-tar color in food. See *United States v. Detroit and Cleveland Navigation Co.*, 326 U.S. 236, 240. He is not required to indulge "in hair-splitting speculation as to whether the amount of poison used may possibly have been so nicely calculated as not to kill or be of immediate serious injury". Landis, J., in *United States v. 1,950 boxes of Macaroni*, 181 Fed. 427 (N.D. Ill.).

As Judge Hastie observed in reviewing other regulations issued by the Department in *Atlas Powder Co. v. Ewing*, 201 F. 2d 347, 355 (C.A. 3):

One making a rule for the future which in practical effect will determine whether millions of people shall eat something every day may reasonably refuse to subject the general public to even slight risks and small deceptions. In these circumstances, the fact that administrative action has

been dominated by great caution but serves to emphasize the reasonableness of the Administrator's conduct.

There, the Administrator excluded from bread a chemical of doubtful safety—even though he was unable to conclude that it was deleterious—on the ground that to permit its use would not “promote honesty and fair dealing in the interest of consumers”.

Here, the Secretary is concerned with chemicals that affect the heart, the liver, and other vital organs; with chemicals that profoundly affect growth processes; with chemicals of established toxicity. At the very least, before such substances are permitted into the national diet on food of widespread use, there should be expert testimony as to permissible tolerances. At the very least, assuming that the opinion below correctly interprets the statute, the Secretary must be presented with evidence that will show that safe tolerances can be established under Section 406(a), and he must consider the use of Red 32 on oranges in connection with the use of coal-tar colors on other products.

The initial determination as to the necessity and possibility of tolerances is for him to make, not the court. As this Court said in *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, 227-228:

The Act does not contemplate that courts should thus substitute their own judgment for that of the Administrator. \* \* \*

\* \* \* Under such provisions we have repeatedly emphasized the scope that must be allowed to the discretion and informed judgment of an expert administrative body [citing cases]. These considerations are especially appropriate where the

review is of regulations of general application adopted by an administrative agency under its rulemaking power in carrying out the policy of a statute with whose enforcement it is charged. \* \* \*

Contrary to this principle, the court below, instead of remanding the case to the Secretary to consider the promulgation of a tolerance for Red 32 on oranges, in accordance with Sections 406(a) and 701, erroneously promulgated the rule itself (R. 186-187).

**CONCLUSION**

For the foregoing reasons, it is submitted that the judgments of the court below should be reversed and the Secretary's order affirmed. Should the Court disagree with our contention that Section 406(a) is wholly inapplicable to coal-tar colors, the judgments of the Court of Appeals should be reversed with instructions to remand the case to the Secretary for appropriate proceedings under Sections 406(a) and 701.

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